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Combination therapy of intra-arterial 5-fluorouracil and systemic pegylated interferon α-2b for advanced hepatocellular carcinoma

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Introduction: Two recent phase III clinical trials have shown that sorafenib, an orally available multikinase inhibitor, improves the median overall survival in patients with advanced hepatocellular carcinoma (HCC). However, patients with HCC and portal vein tumor thrombosis (PVTT) usually have very short survival and grave prognosis even when treated with sorafenib. On the other hand, recent advances in implantable drug delivery systems have made it possible to administer repeated arterial infusion of chemotherapy agent. Compared with systemic chemotherapy, hepatic arterial infusion chemotherapy (HAIC) has the benefits of increasing the local concentration of drugs and reducing systemic side effects. Since 2006, we have treated the patients displaying advanced HCC with PVTT by combining HAIC of 5-fluorouracil (5-FU) and systemic pegylated interferon (PEG-IFN) α-2b, and reported favorable results. In this article, we evaluated the efficacy of combined 5-FU and PEG-IFN α-2b, and compared outcomes between advanced HCC patients with PVTT treated using sorafenib.

Methods: Forty patients with HCC and PVTT were enrolled. Of these, 21 patients were treated using subcutaneous administration of PEG-IFN α-2b and intra-arterial infusion of 5-FU [5-FU/PEG-IFN group], 19 patients were treated using continuous oral treatment with 400-800 mg of sorafenib (consisting of two 100-200 mg tablets) twice daily [Sorafenib group]. We compared the early response to the therapy, progression free survival (PFS) and the cumulative survival rate between these two groups.

Results: The objective early response rate in the 5-FU/PEG-IFN group was significantly higher than that in the Sorafenib group (71.4 vs. 10.5%, P<0.01). The median PFS time of the 5-FU/PEG-IFN and the Sorafenib group were 10.9, and 2.8 months, respectively. The cumulative survival rates at 6, 12, 18, and 24 months, respectively, were 83.8, 77.8, 55.6, and 55.6% in the 5FU/PEG-IFN group, and 68.4, 37.7, 16.2, and 16.2% in the Sorafenib group. The cumulative survival rates was significantly higher in the 5FU/PEG-IFN group than in the Sorafenib group (P=0.03). Serious complications and treatment-related deaths were not observed in the 5FU/PEG-IFN group. On the other hand, the rate of discontinuation of treatment due to adverse events was 36.8% of the patients who were treated sorafenib.

Conclusions: Based on our findings, this newly developed combination therapy may be useful for patients with advanced HCC, although a large-scale randomized controlled study by comparison with Sorafenib is needed to properly evaluate the efficacy of this therapy.

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